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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,317	12/17/2003	Timothy A. Becker	65306-0092	8901

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EXAMINER	
ROGERS, JAMES WILLIAM	

ART UNIT	PAPER NUMBER
1618	

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01/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/738,317	BECKER ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,7,10-17,21,23-32,35 and 37-44* is/are pending in the application.

4a) Of the above claim(s) *38-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,7,10-17,21,23-32,35 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

Election/Restrictions

Applicant's election with traverse of group I in the reply filed on 10/31/2007 is acknowledged. The traversal is on the ground(s) that similar or overlapping searches may be required from each group identified by the examiner. Thus applicants surmise the examiner will be required to search art related to the two groups as part of the analysis of the claims within Groups I. This is not found persuasive because as outlined in the previous office action the combination as claimed does not require the particulars of the subcombination as claimed because the endovascular occlusion can be formed without the use of the exact catheter as in group II, for instance forming an endovascular occlusion by injecting either the alginate or calcium chloride solution through one catheter and then injecting the other solution through a second separate catheter so that the solutions meet at the target site and form an endovascular occlusion. Thus since the scope of the claims are different a separate search would be necessitated for each group and thus be a burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Response to Arguments

Applicant's arguments with respect to the claims rejected under 35 U.S.C. 103(a) have been considered but are moot in view of the new ground(s) of rejection.

Rule 132 Affidavit

The examiner notes the affidavit filed 10/31/2007, which the inventor states his opinion that the alginates purchased from Pronova in US 2001/00331978 could not be known with certainty. However since the rejections incorporating above reference has been withdrawn the affidavit and its remarks is considered moot.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,6-7,10-17,21,23-32 and 35 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically the recitation that the purified alginate liquid is of a molecular weight from **about** 65,000 to **about** 200,000 is not supported by the specification. Applicants only have support for the range 65,000 to 200,000, they do not have support for the broader range claimed.

The word **about** broadens the scope of the range to outside the range supported within the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,17,23 and 25-27 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The molecular weight is indefinite in each claim because the numbered range is unitless. For example are applicants claiming the MW in Da or KDa, further clarification within the claims is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,6,7,10-17,21,23-24,26,35,37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cochrum (US 5,614,204, cited in previous office action) in view of Becker (APPLICATION OF CALCIUM ALGINATE AS AN ENDOVASCULAR EMBOLIZATION MATERIAL FOR VASCULAR LESIONS ,Dissertation, Arizona State University, cited by applicants in Rule 130, 131 or 132 Affidavits).

Cochrum discloses vascular occlusion agents and a method for hemostatic occlusion, alginates can be selected as the angiographic occlusion agent. See abstract and col 3 lin 48-59. In one form of administration the biopolymer solution is injected in liquid form to the site where occlusion is needed and a calcium solution is independently added before, during or after the injection of the biopolymer in order to achieve complete occlusion of the vessel. See col 7 lin 58-65. The injection is by a catheter connected to a syringe with a plunger, the hand controls delivery of the solution. Since the human hand can control the flow rate at the will of the administrator and it is obvious that no matter how steady someone's hand is while injecting the solutions the flow rate

of the solution when delivered by catheter will vary during the injection stage due to human muscle contraction variances. See Fig 1. Therefore applicants limitation that the injection of the alginate/ calcium chloride solution are at variable rates within an injection stage or across injection stages is met by the disclosure of Cochrum. Regarding claims 15-16 Cochrum discloses that the alginate solution may also contain therapeutic agents. See col 13 lin 38-44.

Cochrum while disclosing forming vascular occlusions by injecting alginate and calcium solutions to the site intended for occlusion the reference is silent on the use of purified alginate solutions with a particular molecular weight.

Becker discloses the use of calcium alginate as an endovascular embolization material for vascular lesions. See abstract. Becker is used for the disclosure within on the use of the alginates with purified high guluronic acid content (PHG) purchased from Pronova Biomedical UP-LVG. See pag 8 lin 1-3. Pronova UP-LVG is known to have a molecular weight range of 75,000 to 200,000 g/mol, within applicants claimed range. See NovaMatrix online catalog for Pronova Up LVG included. PHG alginates were disclosed as having optimal material properties compared to other types of alginates such as high mannuronic acid containing alginates. Specifically PHG alginates had adjustable viscosity in liquid form, mechanical stability in sold form and non-adhesive properties. See pages 28-29,31,32,42 and 74 in their entirety. Claim 26 which requires providing a balloon to a targeted area and injecting the alginate liquid is met by Becker, who discloses that one feasible injection technique would include local flow arrest with a proximal balloon catheter and distal retrograde injection of the alginate reactive

components. Regarding claims 35 and 37 since the PHG alginates of Becker are the same as the alginates claimed by applicants it is obvious that the same polymer will have the same properties including viscosity. Also on page 30 of the dissertation a figure of viscosity vs. concentration shows that at 1 wt% PHG appears to have a viscosity less than 25 cP.

It would have been prime facie obvious at the time of the invention to a person of ordinary skill in the art to modify the alginates disclosed in Cochrum and add the PHG alginate (Pronova Up LVG) disclosed within Becker. It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components of compositions intended for vascular occlusion. A person of ordinary skill has good reason to pursuer the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. There is also clear motivation to modify/replace the alginates of Cochrum with the purified PHG alginates of Becker because the PHG alginates of Becker show clear advantages to other alginates in regards to biocompatibility, strength and viscosity. An artists of ordinary skill in the art at the time of applicants claimed invention would have a reasonable expectation of success in modifying/replacing the alginates of Cochrum with the PHG alginates of

Becker because both publications use similar ingredients (alginates and calcium) in their compositions to provide the same disclosed intended use vascular occlusion, therefore the ingredients would be interchangeable. It therefore follows that the instant claims define prime facie obvious subject matter.

Claims 1,6,7,10-17,21,23-32,35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cochrum (US 5,614,204, cited in office action dated 08/10/2005) in view of Becker (APPLICATION OF CALCIUM ALGINATE AS AN ENDOVASCULAR EMBOLIZATION MATERIAL FOR VASCULAR LESIONS, Dissertation, Arizona State University, cited by applicants in Rule 132 Affidavit) in view of Ji et al. (US 5,894,022) in view of Reeves (US 5,222,970).

Cochrum and Becker are disclosed above. Cochrum does not disclose the use of a coil in conjunction with the purified alginate and calcium chloride.

Ji is used only to show that using a polymeric occlusion agent in conjunction with another endovascular embolic material such as a coil was already known at the time of the invention. See col 6 lin 23-38.

Reeves is used only to show that using a catheter to inflate a balloon with a polymer for vascular occlusion was already known at the time of the invention. See abstract and col 6 lin 40-47.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because the combination of Cochrum and Becker as above disclose the same

polymeric alginate composition for vascular occlusion as applicants while Reeves and Ji showed the use of a catheter to inflate a balloon with a polymer for vascular occlusion and use of a polymeric occlusion agent in conjunction with another endovascular embolic material such as a coil were already known at the time of the invention. Thus the claimed invention would have been *prima facie* obvious since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER